

Appl. No. 10/617,078
Response dated October 12, 2006
Reply to Restriction Requirement of September 12, 2006

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REMARKS/ARGUMENTS

Claims 1-29 are pending in this application.

Restriction Requirement

In the Restriction Requirement mailed September 12, 2006, the Office restricted the application to the following Groups of claims:

- I. Claims 1-6 are drawn to the method comprising administering a biodegradable polymeric delivery system with (a) an effective amount of one or more antigens and (b) one or more basic additives, classified in class 424, subclass 426.
- II. Claim 27 is drawn to an immunogenic composition for eliciting an immune response against an antigen as disclosed in relation to method steps in Group I.
- III. Claims 7-26 are drawn to the method comprising administering a biodegradable polymeric delivery system comprising an effective amount of a human chorionic gonadotropin (hCG), classified in class 424, subclass 426.
- IV. Claims 28 and 29 are drawn to an immunogenic composition for eliciting an immune response against human chorionic gonadotropin (hCG) as disclosed in relation to the method steps in Group II (sic), classified in class 424, subclass 426.

Election

Applicants elect group I, *i.e.*, claims 1-6, *with traverse*. With respect to the election of species requirement, Applicants elect the species wherein the polymeric delivery system is poly(D-L-lactide-co-glycolide) (PLGA), the antigen is a peptide, and the basic additive is magnesium carbonate. Claims 1-6 are readable on this election.

The Office makes the case that the claims of groups I, II, III and IV are distinct or independent:

The inventions are independent or distinct, each from the other because:

Inventions I and II are distinct from inventions III and IV in that two distinct products and two associated methods are disclosed respectively. The related inventions are distinct if the (1) inventions as claimed are either not capable of use together or can have a materially different

Appl. No. 10/617,078

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design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed are distinct in that inventions I and II are directed to practicing an immunogenic composition for eliciting an immune response against an antigen related to a method of enhancing immunogenic response thereof. However, inventions III and IV are directed to practicing an immunogenic composition for eliciting an immune response against human chorionic gonadotropin (hCG) related to a method of enhancing a response thereof. These products and methods are related but distinct in that they are not connected in at least one of: design, operation, or effect. In the instant case, these products are distinct in either design or effect. By distinctness in design, Invention I, specifically claim 1, lacks limitations regarding exclusivity to just one antigen and to just one basic additive in comparison to claim 7 of Invention III, which discloses the limitation of (1) human chorionic gonadotropin (hCG) and (1) basic additive. By distinctness in effect, the immunogenic composition for eliciting an immune response against an antigen (Invention II, Claim 27) may reasonably invoke a significantly different initial response if it is not acting directly against a human chorionic gonadotropin antigen and is not acting in concomitance with any other antigen as disclosed in Invention IV, Claim 28. Claim 27 lacks the limitations of Claim 28, i.e., specific ranges, ranges of ratios and direct ratios. The effects of both Inventions I and Invention III are therefore distinct. Furthermore, the Inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Invention I is distinct from invention II. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, Invention I as claimed is drawn to a method comprising administering a biodegradable polymeric delivery system, while invention II is drawn to the instant immunogenic composition for eliciting an immune response against an antigen as disclosed in relation to the method steps in Invention I. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Invention II is distinct from Invention IV. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, Invention III is drawn to a method comprising administering a biodegradable polymeric delivery system comprising an effective amount of a human chorionic gonadotropin (hCG), while invention IV is drawn to an immunologic composition for eliciting an immune response against human chorionic gonadotropin (hCG) as disclosed in relation to method steps in Invention III. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are distinct for the reasons given above and there would be a serious burden on the Examiner if restriction were not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

(Office action of September 12, 2006, pages 3-5, emphasis added.)

Applicant submits that restriction is not proper in this instance. MPEP § 803 states the requirement for a *proper* restriction.

Appl. No. 10/617,078

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There are two criteria for a proper requirement for restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed; and (B) There must be a serious burden on the examiner if restriction is required.

(MPEP § 803, citations omitted, emphasis added.) Thus, there are *two* requirements for restriction: independence or distinctness *and* a serious burden. Both are required; independence or distinctness without a serious burden is not sufficient to justify restriction. Section 803 explicitly states that "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions."

Applicant respectfully submits that restriction is not proper in this case. While the claims of Groups I, II, III, and IV may satisfy the Office's requirements for distinctness or independence, their consideration would hardly result in a serious burden on the Office. Groups I, II, III, and IV are, in fact, classified in the same class and subclass. Applicants respectfully request that the restriction requirement be withdrawn.

If issues relating to this application can be resolved by discussion, the Examiner is invited to contact the undersigned attorney by telephone.

Respectfully submitted,

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